ESTIMATION OF EXPOSURE OF PERSONS IN CALIFORNIA TO PESTICIDE PRODUCTS THAT CONTAIN DELTAMETHRIN

by

Thomas Thongsinthusak, Staff Toxicologist

HS-1732 December 3, 1996

California Environmental Protection Agency
Department of Pesticide Regulation
Worker Health and Safety Branch
1020 N Street, Sacramento, CA 95814-5624

ABSTRACT

Deltamethrin is a new active ingredient for use in controlling various pests in cotton fields, homes, structures and institutions. The major urinary metabolite of deltamethrin in rats dosed orally is the sulfate conjugate of 4'-hydroxy-phenoxybenzoic acid. A mean dermal absorption rate obtained from a study in male rats was 6.7%. Estimated absorbed daily dosages (ADD, μg/kg/day) that resulted from an aerial application of Decis® 0.2 EC in cotton were 0.46 for mixer/loaders, 0.25 for applicators and 0.03 for flaggers. For groundboom application of Decis® 0.2 EC, the ADD (μg/kg/day) for mixer/loaders was 0.42 and that for applicators was 0.05. Cotton scouts would be experiencing an ADD of 0.22 μg/kg/day when gloves are not used or 0.13 μg/kg/day when gloves are used. The exposure estimates for workers handling Decis® 1.5 EC was approximately 30% higher because of a higher maximum application rate. Infants playing on treated surfaces, where deltamethrin was applied by pest control operators, would experience high exposure potential. ADDs for infants and adults playing in treated rooms or contacting treated surfaces were 11.1 and 7.1 μg/kg/day, respectively. A pest control operator would experience an ADD of 43.2 μg/kg/day when applying deltamethrin emulsion to residences or buildings and 0.80 μg/kg/day when applying deltamethrin dust to ornamentals. Deltamethrin is in the risk assessment process because of possible adverse health effects to humans. Deltamethrin has been shown to cause autonomic nervous system dysfunction (acute toxicity), abnormal gate, trembling, vomiting and liquid feces (sub-chronic toxicity), and nervous degeneration (chronic toxicity) in experimental animals.

This report was prepared for use in the Department's Risk Characterization Document for deltamethrin.

California Environmental Protection Agency
Department of Pesticide Regulation
Worker Health and Safety Branch

Human Exposure Assessment

Deltamethrin

December 3, 1996

INTRODUCTION

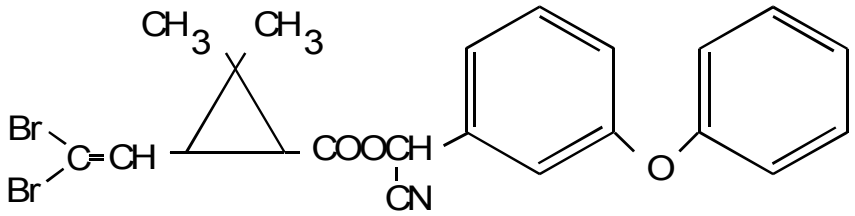
Human pesticide exposure assessment provides essential information for the risk assessment process. The exposure estimates contained in this document will be used in the risk characterization document of the Department of Pesticide Regulation (DPR). The exposure levels will also be used as a basis for developing mitigation proposals if exposures to deltamethrin are found to cause excessive risk.

Deltamethrin is a new active ingredient (a.i.) in five products: Delta Tech, Decis® 0.2 EC, Decis® 1.5 EC, K-Othrine® SC, and K-Othrine® Dust. Registrants have recently applied for registration of these five products in California. In addition to exposure estimates, presentation of other properties of deltamethrin are necessary for a better understanding of its nature, usage and effects. These additional categories are physical and chemical properties, regulatory history, technical and product formulations, label precautions, usage, worker illnesses, dermal sensitization, pharmacokinetics/animal metabolism, and dermal absorption.

PHYSICAL AND CHEMICAL PROPERTIES

(Grelet, 1990; Lambert 1991)

1.	Chemical Name:	(1R,3R) [α-cyano(3-phenoxyphenyl)methyl] 3-(2,2-dibromo-ethenyl)-2,2-dimethylcyclopropanecarboxylate (IUPAC)
2.	Common Name:	Deltamethrin
3.	Trade Names:	Butoflin™; Butox™; Decis™; K-Othrin™; K-Othrine™ Dust; Striker™ IEC insecticide
4.	Structural Formula:	



5.	Empirical Formula:	$C_{22}H_{19}Br_2NO_3$
6.	CAS Registry Number:	52918-63-5
7.	Molecular Weight:	505.2 gm/mole
8.	Specific Gravity:	1.053 gm per mL at 20°C (Decis®) 0.5 gm per mL at 20°C (Technical Grade of AI, TGAI)
9.	Physical State:	White to beige crystalline powder (TGAI)

10.	Boiling Point:	Not applicable
11.	Solubility:	Soluble in acetone, dimethylformamide, dioxane, ethyl acetate, and toluene (all 23 - 39%), relatively insoluble in water (i.e., 0.2 ppb in 24 hours)
12.	Vapor Pressure:	1.5×10^{-8} mmHg at 25°C (> 90% AI)
13.	Octanol/Water Partition Coefficient:	2.7×10^{5} at 25°C
14.	Henry's Law Constant:	2.7×10^{-6} atm/m^3 per mole
15.	pH:	5.9 (in a 1% aqueous dispersion)(TGAI)

REGULATORY HISTORY

No deltamethrin products are currently registered in California.

TECHNICAL AND PRODUCT FORMULATIONS

Deltamethrin is the a.i. used in a number commercial insecticide products. Products containing deltamethrin include Butoflin, Butoss, Butox, Cislin, Crackdown, Cresus, Decis®, Decis®-Prime, K-Othrine®, and K-Otek.

As of 1996, AgrEvo USA Company submitted a request to DPR to register five deltamethrin products in California. These products are shown in Table 1.

Table 1. Deltamethrin products.

Product Name	**Active Ingredient (%)**
1. Delta Tech (EPA Reg. No. 432-762)	98.0
2. Decis® 0.2 EC (EPA Reg. No. 34147-8)	2.86 (0.2 lb a.i./U.S. gallon)
3. Decis® 1.5 EC (EPA Reg. No. 34147-12-45639)	16.6 (1.5 lb a.i./U.S. gallon)
4. K-Othrine® SC Insecticide (EPA Reg. No. 432-763)	4.75
5. K-Othrine® Dust Insecticide (EPA Reg. No. 432-772)	0.05

LABEL PRECAUTIONS

Decis® 1.5 EC is a Toxicity Category I pesticide with a signal word "DANGER." The label indicates that this product is hazardous to humans and domestic animals. It is corrosive and is fatal if swallowed. It can cause irreversible eye damage and skin burns. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. The product label also indicates that skin exposure may result in a sensation described as tingling, itching, burning, or prickly feeling. Onset may occur immediately and up to 4 hours after exposure and may last from 2 to 30 hours, without damage. Appropriate personal hygiene should be observed when using this product. Handlers, who may be exposed to the tank mix through application or other tasks, must wear: coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear for overhead exposure. In addition, a chemical-resistant apron is required when mixing or loading, or cleaning equipment. Handlers, who may be exposed to the concentrate through mixing, loading, application, or other tasks, must wear: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear for overhead exposure. In addition, a chemical-resistant apron is required when mixing or loading, or cleaning equipment. When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler personal protective equipment (PPE) requirements may be reduced or modified as specified in the WPS. PPE required for early entry to treated fields are: coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear for overhead exposure, and protective eyewear.

Decis® 0.2 EC is also a Toxicity Category I pesticide with a signal word "DANGER." PPE requirements for handlers and early entry workers are the same as those for Decis® 1.5 EC. Delta Tech is a Toxicity Category II pesticide with a signal word "WARNING." This product is for formulation purposes only.

K-Othrine® SC Insecticide is a Toxicity Category III pesticide with a signal word "CAUTION." This product is recommended for use by pest control operators and/or commercial applicators. PPE requirements were not stated on the label. K-Othrine® Dust Insecticide is a Toxicity Category III pesticide with a signal word "CAUTION." This appears to be a home use product. PPE requirements were not stated on the label.

USAGE

The primary use of deltamethrin (approximately 85% of the total production) is for crop protection (WHO, 1990). Deltamethrin is also used to protect stored commodities such as cereals, grains, and coffee beans. Other uses include insect control for public health concerns, forestry, animal facilities, for animal ectoparasites, and as a wood preservative (WHO, 1990; Hartley Agrochem HDBK, 1987).

While the initial California registration application is for the technical material (to be used in formulating products), anticipated California end-product uses include: treatment of cotton, residential and institutional establishments, non-food/feed areas of food/feed processing plants, granaries, and ornamental plants.

WORKER ILLNESSES

Since deltamethrin has not been registered in California, there is no record of human illnesses resulting from its use in pest control. There were, however, three reported illness cases caused by accidental ingestion of an unregistered deltamethrin product (Verder-Carlos, 1996). The first two cases involved two sisters who allegedly ingested "Miraculous insecticide chalk." They mistook it for a bar of vitamins. The reported symptoms were dizziness, nausea and abdominal pain. The third case involved a child that mistook a deltamethrin product for candy and ate it. The observed symptoms were lethargy and slightly unsteady gait.

The toxicity of deltamethrin to humans has been documented in China. He *et al*. (1989) have reported 325 cases of deltamethrin poisonings due to agricultural use and accidental or suicidal poisoning. Oral ingestion has been associated with epigastric pain, nausea, vomiting, coarse muscular fasciculation, and coma. Workers exposed to deltamethrin during its manufacture experienced cutaneous and mucous membrane irritation.

DERMAL SENSITIZATION

A study of dermal sensitization of Decis® 0.2 EC (also known as Decis® 2.5 EC) was performed in 8-week-old, young adult Hartley-albino guinea pigs by using the Buehler technique (Buehler, 1983). The animals used comprised three groups: untreated control (no induction), positive control (induced with 2,4-dinitrochlorobenzene, 2,4-DNCB) and the test substance group (induced with deltamethrin solution) (Myer, 1990). Five male and five female animals were employed for each of the untreated and positive control groups. The test substance group used ten males and ten females. This study was conducted in compliance with the U.S. EPA Good Laboratory Practice standards.

Doses of the deltamethrin for induction and challenge phases were determined from an irritation screening study. The dose for the induction phase was 0.4 mL of 2.5% deltamethrin in deionized water and that for the challenge phase was 0.4 mL of 2.0% deltamethrin emulsion. For the positive control, 0.4 mL of 0.1% 2,4-DNCB in acetone was used for the induction phase and that for the challenge phase was 0.4 mL of 0.05% 2,4-DNCB solution. The same concentration of deltamethrin used in the challenge phase was also used for the concurrent control group.

Left shoulders of the test animals were clipped free of hair with an electric clipper prior to administration of the dose. The dose was applied to a 20 x 20 mm Webril pad. The pad was then applied to the shoulder and the treated sites occluded. After a six-hour exposure, the occluded pad was removed. The application was repeated two more times in the same manner on days 7 and 14. For the challenge phase, the left flank of each animal was clipped free of hair with an electric clipper. The animals of the untreated control and the test substance group were challenged on day 28 with deltamethrin emulsion and the positive controls were challenged with 2,4-DNCB solution. The contact period was six hours. The test sites were evaluated for irritation approximately 24 and 48 hours after the challenge exposure.

The results showed that there were no positive signs of erythema (score ≥1) at the test site of the test substance group or in concurrent control group. Low level (grade 0.5) erythema was seen in two test substance animals at 24 and/or 48 hours and one in an concurrent control animal at the 24-hour observation period. All animals treated with 2,4-DNCB solution exhibited positive scores (≥1) with edema at both the 24 and 48 hour observation intervals.

(Notes: 0 = no reaction, ± (0.5) = slight, patchy erythema, 1 = slight confluent or moderate, but patchy erythema, 2= moderate confluent erythema, 3= severe erythema with or without edema).

The average scores were 2.3 and 1.8 for the 24- and 48-hour observation intervals, respectively. Based on the results obtained from this study Decis® 2.5 EC was not considered a sensitizing agent in Hartley-albino guinea pigs. The same technique was also employed for the study of dermal sensitization of undiluted deltamethrin (99.2%) (Myer, 1989). Based on the results obtained, deltamethrin was not considered a sensitizing agent in Hartley-albino guinea pigs.

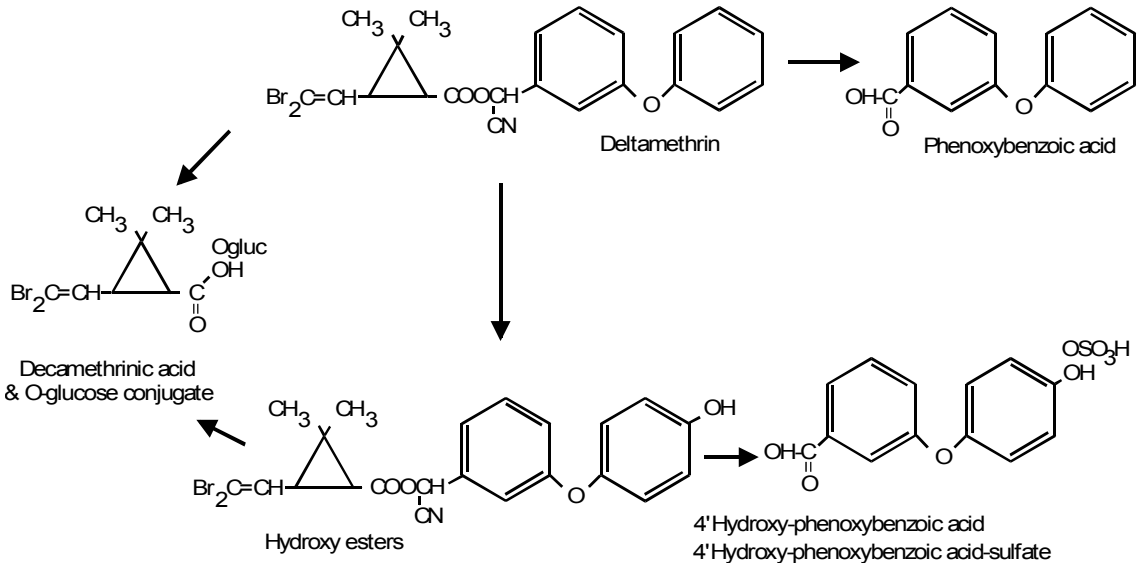
A modification of the Buehler method (Buehler, 1965) was employed in the dermal sensitization test for deltamethrin SC 50 gm/L in Hartley-albino guinea pigs (Kuhn, 1990). Animals in a positive control group were treated with 0.5 mL of a 0.06% solution of 2,4-DNCB in ethanol. Animals in the test group were treated with 0.5 mL of the undiluted test material. During the induction phase which spanned 22 days, animals were treated 10 different times. On day 36, animals were challenged with the same dose as in the induction phase. Observations were made 24 and 48 hours after the challenge treatment. Results obtained indicated that the test material, deltamethrin SC 50 gm/L, did not produce a sensitizing reaction in guinea pigs.

An interim report on a dermal sensitization study of 2.4% deltamethrin was submitted to the Department in January 1995 (Soto, 1995). However, a final report has not been submitted to the Department. The interim report did not present results of positive control. The Buehler technique was employed in this study. The results of the test for animals that were challenged with 25% solution were: five animals had a score of 1, two showed a score of 2, twelve animals indicated scores of 0.5, and one displayed no reaction. A definite conclusion cannot be made at this time because a final report has not been submitted. However, from this and other studies it is unlikely that deltamethrin is a dermal sensitizer.

PHARMACOKINETICS/METABOLISM

Metabolism in the rat: The metabolism of deltamethrin by the rat has been extensively studied by Cole, *et al.* (1982) and Bosch (1990). Deltamethrin is hydroxylated at the 2', 4' and 5 positions of the alcohol moiety and the methyl group trans to the carboxylate linkage; extensive ester cleavage of deltamethrin yields a series of alcohols and carboxylic acids and their glucuronide, glycine, and sulfate conjugates. The proposed metabolic pathway is shown below.

Deltamehtrin: Proposed Metabolic Pathway in Rats.



Metabolism of ^{14}C-deltamethrin was studied in male and female rats dosed orally with ^{14}C-deltamethrin labeled in two positions (^{14}C-benzyl at 59.2 mCi/mmol or ^{14}C-dimethyl deltamethrin at 60 mCi/mmol) (Bosch, 1990). Groups of 5 Crl:CD(SD)BR rats per sex were given 0.55 mg/kg (single oral dose), 0.55 mg/kg (14 nonradiolabeled doses followed by a radio labeled dose on day 15) or 5.50 mg/kg (single oral dose). It was shown that most of the radioactivity was excreted in the urine and feces within 24 hours of dosing and that tissue and carcass residues were less than 2% of the dose at 7 days. Of that remaining, most was stored in the fat; for the low dose groups, radioactivity concentrations ranged from 0.047 to 0.093 ppm in the fat. For the high doses, these values ranged from 0.504 to 0.840 ppm. Rats dosed with ^{14}C-benzyl deltamethrin had 30 to 49% excreted in the urine as the sulfate conjugate 4'SO_4-mPBAcid and 2% to 4% as unconjugated mPBAcid. In the feces, 17 to 46% was excreted as deltamethrin (the higher dosage rats excreted a higher percentage in the feces as deltamethrin and a lower percentage in the urine as 4'SO_4-mPBAcid). For rats dosed with ^{14}C-dimethyl deltamethrin, 22 to 38% of the dose was excreted in the urine as the glucuronide conjugate Br_2CA-glucuronide and 4 to 10% as the unconjugated Br_2CA; in the feces, 21 to 35% was excreted as deltamethrin.

Metabolism in the mouse: Metabolic studies on deltamethrin have also been performed in mice (WHO, 1990). The major metabolic pathways in mice were similar, but not identical to those in rats. One of the differences seen in mice was the presence of more unchanged deltamethrin in the feces. In mouse feces, there were 4 monohydroxy ester metabolites (2'-OH-, 4'-OH-, 5-OH- and trans-OH-deltamethrin) and one dihydroxy metabolite (4'-OH-*trans*-OH-deltamethrin) that were not found in mouse urine. Major metabolites from the acid moiety in mice were Br_2CA, *trans*-OH-Br_2CA (only detected in mice), and their glucuronide and sulfate conjugates. Much larger amounts of *trans*-OH-Br_2CA and its conjugates were formed in mice and a major metabolite of the alcohol moiety in mice was the taurine conjugate of PBacid in the urine, which is not detected in rats. Mice also tend to produce less phenolic compounds compared to rats. Other metabolites found in mice, but not rats include 3-phenoxy benzaldehyde (PBald), 3-phenoxy benzyl alcohol (PBalc), and its glucuronide, and glucuronide of 3-(-4-hydroxy phenoxy) benzyl alcohol (4'-OH-PBalc) and 5-hydroxy-3-phenoxy benzoic acid (5-OH-PBacid).

Metabolism in humans: Studies of deltamethrin metabolism have been performed in human volunteers (WHO, 1990). Each of three young males received a single oral dose of 3 mg of ^{14}C-deltamethrin mixed in 1 gm of glucose and diluted in 10 mL polyethylene glycol 300 and then in 150 mL water (total radioactivity was 1.8 ± 0.9 mBq). Samples of blood, urine, saliva and feces were collected at intervals over a 5-day period. Clinical and biological examinations, performed every 12 hours during the trial and one week after termination, revealed no abnormal findings. The peak plasma radioactivity appeared between 1 and 2 hours after administration and remained over the detection limit (0.2 Kbq/l) during the next 48 hours. Apparent elimination half-life was between 10.0 and 11.5 hours and the radiolabel detected in blood cells and saliva was extremely low. Urinary excretion was about 50% of the initial radioactivity and 90% of the radiolabel was excreted during the 24 hours following administration. The apparent half-life of urinary excretion was 10.0 to 13.5 hours (consistent with plasma levels). Fecal elimination at the end of the observation period represented 10-26% of the dose and the total of fecal plus urine elimination was approximately 64 to 77% of the initial dose after 96 hours.

Oral absorption: The extent of absorption following oral exposure to a chemical can be estimated on the basis of excretion analysis following oral and intravenous (i.v.) exposures (i.e., if the i.v. exposure is assumed to represent 100% absorption, then the extent of absorption following oral exposure is the percent urinary excretion after oral exposure divided by the percent of urinary excretion after i.v. exposure).

$$\text{Extent of absorption} = \frac{\%\ \text{urinary excretion}\ (\text{oral study})}{\%\ \text{urianry excretion}\ (\text{i. v. study})}$$

For deltamethrin, the estimated absorption was based on the metabolism and excretion of tralomethrin by SD rats (Tanoue 1988). The use of tralomethrin data as surrogate for deltamethrin was considered appropriate since tralomethrin is rapidly and completely debrominated to form deltamethrin in the G.I. tract. Five male and 5 female SD rats were used for the oral dosing portion of the test while 7 to 8 males were used for the i.v. portion of the study. Animals were treated with ^{14}C-labeled acid, alcohol, or cyano tralomethrin at a concentration of 0.3 mg/kg. Urine and feces were collected at 24-hour intervals until the animals were killed (after 4 days for the acid and alcohol moieties, and 7 days for the CN moiety). Oral dosages of 0.3 mg/kg of tralomethrin ^{14}C-labeled at the acid, alcohol or CN moiety resulted in urinary excretion of 43.9, 46.0 and 14.6%, respectively. For i.v. administration, the corresponding urinary excretion was 69.1, 75.7 and 28.7%, respectively. The final extent of absorption values were, therefore, 63.5, 60.8 and 50.9% for the acid, alcohol and CN-labeled tralomethrin, respectively (Table 2). On the basis of these excretion values, oral absorption is assumed to be 58%.

Table 2. Deltamethrin oral absorption estimates based on tralomethrin metabolism and urinary excretion studies in rats.

Deltamethrin oral absorption estimate[1,2]				
^{14}C-labeled tralomethrin	% Urinary excretion Oral study	i.v. study	% Oral absorption	Mean
acid	43.9	69.1	63.5	
alcohol	46.0	75.7	60.8	58.4
cyano	14.6	28.7	50.9	

[1] Extent of absorption $= \frac{\%\ \text{urinary excretion}_{\text{(oral study)}}}{\%\ \text{urianry excretion}_{\text{(i.v. study)}}}$

[2] Tanoue, 1988

The extent of oral absorption can also be roughly estimated on the basis of fecal excretion measurements from the Tanoue (1988) study. Following oral administration, the test material found in the feces can be assumed to have either passed through unabsorbed or absorbed and delivered to the feces through the bile duct. Following i.v. administration (which is assumed to represent 100% absorption), the test material found in the feces is the result of absorption. For example, Tanoue reported that after i.v. exposure, 26.9% of the administered dose of the acid-tralomethrin was excreted in the feces (i.e., 26.9% of the absorbed dose was excreted in feces). He also reported that after oral exposure, 54.7% of the administered dose of the acid-tralomethrin was excreted in the feces. On the basis of the reported values and the indicated assumptions, the following equation can be generated:

$$\%\ fecal\ excretion_{(oral\ study)} = \%\ absorbed\ and\ excreted\ in\ bile + \%\ not\ absorbed$$

$$or\ \ 54.7\% = (total\ absorbed \times 0.269) + (100 - total\ absorbed)$$

$$then\ \ \ total\ absorbed = 61.9\%$$

This procedure was performed for each of the tralomethrin moieties. The results are presented in Table 3:

Table 3. Deltamethrin oral absorption estimates based on tralomethrin metabolism and fecal excretion studies in rats.

Deltamethrin oral absorption estimate[1,2]				
^{14}C-labeled tralomethrin	% Fecal excretion Oral study	i.v. study	Oral absorption	Mean
acid	54.7	26.9	61.9	
alcohol	52.4	19.2	58.9	52.3
cyano	71.7	24.3	37.4	

[1] (A x I)+(100 - A) = O, where A= absorption, I= excretion in i.v. study, and O= excretion in oral study.

[2] Tanoue,1988

As indicated, oral absorption of deltamethrin is assumed to be approximately 52% on the basis of fecal excretion in rats.

For this risk assessment, the oral absorption of deltamethrin is assumed to be 58%. This is based on the above urinary excretion studies and supported by the fecal excretion calculations.

DERMAL ABSORPTION

A dermal absorption study of deltamethrin in male rats was conducted by Hazleton Wisconsin, Inc. (Ampofo, 1995). The study was performed in compliance with Good Laboratory Practice standards. Approximately seven-week-old male Sprague-Dawley rats (Charles River Crl:CD®BR) were used in the definitive phase of the study. Body weights of these rats ranged from 135 to 198 grams. These animals were inspected and acclimatized for at least 7 days prior to the study. One day prior to the study, the backs and shoulders of each rat were shaved, and the shaved areas were washed with acetone. A plastic enclosure was affixed to the shaved area to define the treated area, which was approximately 12.5 cm^2. An Elizabethan collar was placed on the animal's neck to prevent ingestion of the test material.

Three dose levels and one control were used in the definitive phase of the study. The dose was prepared by combining known amounts of high purity ^{14}C-deltamethrin (>95% pure), water, concentrate (Deltamethrin SC5 4.76%), and blank formulation. Water was used for the control group. Approximately 100 µL (except for the 0.015 mg/animal group) of the dose was applied within the plastic enclosure. The average doses were 1.70, 0.551, and 0.015 mg/animal equivalent to 136, 44, and 1.23 µg/cm^2, respectively After administration of the test material, the treated skin site was covered with a nonocclusive device made with filter paper.

The treated skin sites were washed with a 2% soap solution immediately before the scheduled sacrifice times or at ten hours post dose for the 24- and 120-hour sacrifice times. The sacrifice times for the definitive phase of the study were: 0.5, 1, 2, 4, 10, 24, and 120 hours. Daily urine and feces samples, except for the shorter sacrifice times, were collected and analyzed separately. Samples collected for analysis were: spreader rinse, nonocclusive covers, dose enclosures, skin wash, treated skin sites, cage wash, cage wipe, carcass, blood, feces, and urine. Mass balance of the administered dose for animals dosed at 0.015 mg/animal (1.23 µg/cm^2) was very low, ranging from 22.8 to 40.6%. This was because a very low dose was actually administered to animals in this group. The radioactivity short fall was recovered by thoroughly washing the dose vial. As

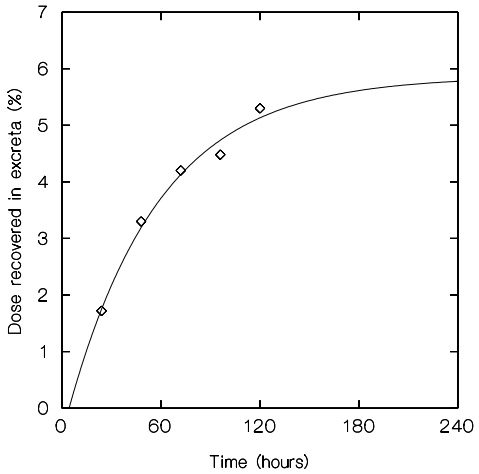
stated in the report, radioactivity in the dose was accounted for within 4% of the original radioactivity level, thereby justifying the use of radioactivity recovered from each rat as the amount of dose actually received. Percent radioactivity for each rat was therefore normalized to the radioactivity recovery for the individual animal.

The results of the study are summarized in Appendix A (Tables A1, A2, and A3). The results in Table A1 indicated that the treated skin sites in these dose groups retained the high percentage of the applied dose, ranging from 4.1 to 17%. There was a very low level of the applied dose recovered in the blood. Excretion of deltamethrin in urine and feces was relatively slow. Less than 1% of the applied dose was excreted for the two higher doses and 1.3% for the lowest dose within 24 hours post dose.

Excretion kinetics of deltamethrin in urine and feces from treated rats were observed for 120 hours after dosing. Percent of dose excreted at different time intervals were tabulated (Table A2). In order to resolve the issue of bound skin residue, cumulative percent dose in urine and feces for different time intervals extrapolated beyond 120 hours were used for estimating the asymptote by employing an exponential saturation model with lag time. An equation representing this model is: Y = A*(1-EXP(-B*(X+C))) or Recov = Max*(1-EXP(-Rate*(Time+Lag))). An example of the plots and the outputs for the lowest dose generated by Intelligent Software Systat® (Systat®, Inc., 1994) are shown in Figure 1. The dermal absorption value is the sum of percent dose at asymptote (maximum or "A" term) and percent of dose recovered in carcass, blood, and cage wash/cage wipe. Table A3 summarizes the dermal absorption values for low, medium and high doses obtained from this study. The adjusted dermal absorption values were 6.8% and 6.5% for the low and medium dose, respectively. Since these two values are very similar, an average dermal absorption value of 6.7% is used in the estimation of absorbed dose. This dermal absorption will cover a wide exposure ranging from 1.23 to 44 μg/cm^2. This exposure range should be representative for the exposure experienced by agricultural workers or consumers.

Figure 1. Asymptotic plot of cumulative dose excreted in urine and feces after topical administration of deltamethrin at 0.015 mg/rat (1.23 μg/cm^2)

$$Y = 5.862*(1-EXP(-0.018*(X-4.316)))$$



Statistics:

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ITERATION	LOSS	PARAMETER VALUES		
0	.9316713D+01	.5000D+01	.1000D-01	.3000D+01
1	.3352108D+00	.5992D+01	.1607D-01	.3929D+01
2	.1678466D+00	.6884D+01	.1141D-01	.4448D+01
3	.1602631D+00	.6591D+01	.1255D-01	.3403D+01
4	.1327319D+00	.6371D+01	.1438D-01	-.6786D+00
5	.1172191D+00	.6056D+01	.1689D-01	-.3976D+01
6	.1121173D+00	.5856D+01	.1817D-01	-.4223D+01
7	.1111450D+00	.5861D+01	.1812D-01	-.4293D+01
8	.1111301D+00	.5862D+01	.1813D-01	-.4322D+01
9	.1111297D+00	.5862D+01	.1813D-01	-.4317D+01
10	.1111297D+00	.5862D+01	.1813D-01	-.4316D+01
11	.1111297D+00	.5862D+01	.1813D-01	-.4316D+01

DEPENDENT VARIABLE IS RECOV

SOURCE	SUM-OF-SQUARES	DF	MEAN-SQUARE
REGRESSION	79.538	3	26.513
RESIDUAL	0.111	2	0.056
TOTAL	79.649	5	
CORRECTED	7.449	4	

RAW R-SQUARED (1-RESIDUAL/TOTAL) = 0.999

CORRECTED R-SQUARED (1-RESIDUAL/CORRECTED) = 0.985

PARAMETER	ESTIMATE	A.S.E.	LOWER <95%>	UPPER
MAX	5.862	0.629	3.156	8.568
RATE	0.018	0.006	-0.006	0.043
LAG	-4.316	5.938	-29.866	21.234

ASYMPTOTIC CORRELATION MATRIX OF PARAMETERS

	MAX	RATE	LAG
MAX	1.000		
RATE	-0.944	1.000	
LAG	0.667	-0.835	1.000

EXPOSURE ASSESSMENT

The registrant, Hoechst Roussel, has submitted two deltamethrin worker exposure studies to the Department. One study was exposure of handlers of Decis® 5.0 EC during aerial applications to cotton fields (Hoechst-Roussel, 1992). The other study was exposure of applicators during application to institutional and residential buildings (Kozar *et al.*, 1981). Other exposure estimates contained in this document were derived from surrogate studies. The exposure estimates for flaggers during aerial application and that for mixer/loaders and applicators during groundboom application were obtained from the Pesticide Handlers Exposure Database (PHED) (U.S. EPA, HWC, and NACA, 1995). Dislodgeable foliar residue (DFR) data for deltamethrin on cotton foliage were obtained from a published study (Estesen *et al*., 1979). The DFR data and transfer factors (TF) from the studies of Ware *et al.* (1973, 1974, 1975) were used for the estimation of exposure for cotton scouts. The latter studies were previously evaluated by Dong *et al.* (1991). Exposures of home occupants (adults and infants) were estimated from a dislodgeable residue study of a broadcast application of deltamethrin (Maxey *et al*., 1995).

The exposure data obtained from surrogate studies, as shown in subsequent sections, were adjusted whenever applicable for factors related to the use of deltamethrin products, such as application rate, clothing protection, default body weight and dermal absorption rate.

Default factors were employed for different work tasks and exposure scenarios whenever compound-specific data were not available. Actual factors, if available from exposure studies, were used instead of default values. Default factors for adult males used in the exposure estimation were: body weight (75.9 kg), surface area (19,400 cm^2) and ventilation rate for light work (14 L/min) (Thongsinthusak *et al*., 1993a). These values were adopted from U.S. EPA (1985) with some adjustment for surface areas of body parts based upon U.S. EPA guidelines (U.S. EPA, 1987). Default factors for adult females were: body weight (61.5 kg), surface area (16,900 cm^2), and ventilation rate for light work (8 L/min) (Thongsinthusak *et al*., 1993a). A dermal absorption value for human exposure assessment was determined to be 6.7%. Default inhalation uptake/absorption is 50% (Raabe, 1988). Default clothing penetration/protection were taken from Thongsinthusak *et al*., (1993a).

I. Use of deltamethrin in agricultural pest control: Decis® 0.2 EC and Decis® 1.5 EC

A. Agriculture: aerial application

A field exposure study was performed in Canada to determine the exposure levels of handlers to deltamethrin (Hoechst-Roussel, 1992). Diluted Decis® 5.0 EC in water was applied at a rate of 4 gm a.i./acre (0.0088 lb a.i./acre). The application volume of the finished spray was 1.17 gallons/acre (4.4 L/acre). Fields of various grain crops were sprayed using a typical fixed-wing aircraft. Eight replicates, each for mixer/loader or applicator exposure monitoring, were performed at each of two sites (Yorkton and Moose Jaw) in Saskatchewan, Canada. Workers wore conventional work clothing, which were long-sleeved coveralls/flight suits or long pants and shirts, shoes or boots, respirators, goggles and caps. Mixer/loaders wore chemical-resistant gloves, whereas pilots wore fire-resistant gloves. Dermal exposure (exclusive of the feet, face, front of neck, and hands) was estimated from residues on 100% cotton long union suits worn underneath each worker's conventional clothing. Exposure to the feet was estimated from residues on 80% cotton/20% polyester short anklet socks worn underneath typical work socks. Exposure of the head and face, "V" of the chest, and back of the neck was estimated from residues on 100% cotton glove fabric dosimeter with exposed surface area of approximately 60 cm^2 each. These dosimeters were attached to the worker's hat (or pilot's helmet), just to the right of the center of the "V" of the chest, and back of the neck. Exposure of the hands protected under chemical- or fire-resistant gloves worn by mixer/loaders and pilots, respectively, was estimated from the protected bare hand and the protected cotton glove worn additionally on the other hand. Residues on the bare hand were measured by washing three times with a 250 aliquot each of 1:1 distilled water:isopropanol solution. All measured residues from each type of dosimeter were adjusted with the corresponding mean recoveries (ranging from 92% to 105%) from field fortification, which was done using Decis® 5.0 EC diluted in water.

Inhalation exposure was monitored during the operation by using 600-mg organic vapor charcoal tubes, which were attached to personal air pumps. However, these samples were not analyzed because the analytical lab could not find a suitable solvent for extracting deltamethrin residues from charcoal tubes. Inhalation exposure of mixer/loaders and applicators during aerial application of chlorothalonil (Thongsinthusak, 1993c) was used as a surrogate.

The number of days per use season for insecticide in cotton was determined to be 62 days (Thongsinthusak *et al*., 1993b). This use period was determined from a report given by Meinders *et al*. (1991). The number of workdays per season or per year is 50 days (Hoechst-Roussel, 1992). Workdays for various work tasks are shown where appropriate in the table footnotes.

A.1 Mixer/loaders (M/L)

Eight mixer/loaders were monitored with a total of sixteen replicates at two sites. Each replicate consisted of mixing/loading one to three tank loads of diluted Decis® 5.0 EC. During the work activity, each mixer/loader partially filled the metal mixing drum with water using a hose connected to a water storage tank. He poured the desired volume of test material directly from its container(s) into the mixing drum or he measured the appropriate volume into a plastic beaker then added it to the drum. He then triple-rinsed empty test product containers and beakers into the metal drum using a hose, and topped off the drum with water. The mixture was then pumped to the spray tank; additional water was pumped through the drum to the spray tank to top it off. The task of the mixer/loader was completed after uncoupling the feed hose and pulling it away from the airplane. There were two replicates in which aircraft were loaded using typical open-pour loading equipment, where a mixer/loader measured a formulation into a plastic beaker, walked along the wing of the aircraft to the hatch of the spray tank and poured the content of the beaker directly through the hatch into the spray tank. Water was then filled to the mark of the

tank. The amount of deltamethrin handled per replicate ranged from 0.31 to 3 kg a.i. (0.7-6.6 lb). The monitoring time averaged about 30 minutes per replicate. The mixing tank consisted of a 200-L metal drum from which the mixed formulation was pumped into the spray tank. Each mixer was assumed to have provided service to two planes covering an application of about 1,000 acres per day (Haskell, 1996). Exposure estimates are shown in Table 4. Absorbed dosages (ADD - Absorbed Daily Dosage; SADD - Seasonal Average Daily Dosage; AADD - Annual Average Daily Dosage; LADD - Lifetime Average Daily Dosage) are shown in Table 5.

A.2 Applicator (A)

Eight applicators (pilots) were monitored for a total of sixteen replicates at two sites. Each replicate consisted of applying one to three tank loads of diluted Decis® 5.0 EC. The monitoring time averaged about 30 minutes per replicate. Each pilot was assumed to have treated 500 acres per day. Five different types of fixed-wing aircraft were used. The aircraft had 450 to 600-L stainless steel tanks. Each spray boom was equipped with 22-30 D6/C45 nozzles and was operated at an altitude of about 2.5-3 meters. Results of the exposure studies are shown in Table 4. Absorbed dosages are shown in Table 5.

Table 4. Dermal/inhalation exposure of mixer/loaders and applicators to deltamethrin by body region during aerial application of Decis® 0.2 EC[a].

	Dermal/inhalation exposure (Average ± SD)			
	Mixer/loaders		Applicators	
Body part	(µg/kg BW/lb a.i.)	(µg/person/day)[b]	(µg/kg BW/lb a.i.)	(µg/person/day)[c]
Feet	0.024 ± 0.016		0.025 ± 0.021	
Upper + Lower body	0.016 ± 0.030		0.133 ± 0.261	
Hands (Hand wash + Gloves)	0.112 ± 0.231		0.149 ± 0.197	
Head[d] + "V"[e] + Neck	0.054 ± 0.059[f]		0.046 ± 0.047	
Total dermal exposure	0.206 ± 0.243[f]	310 ± 369[g]	0.353 ± 0.385	268 ± 292[h]
Inhalation exposure	0.019 ±0.008	28.8 ± 12.1[g]	0.0019 ± 0.0006	1.4 ± 0.5[h]

[a] Decis® 5.0 EC application rate = 0.0088 lb a.i./acre. Maximum Decis® 0.2 EC application rate = 0.02 lb a.i./acre.
[b] A M/L handled 20 lb a.i./day enough to treat 1,000 acres (Haskell, 1996).
[c] A pilot applied 10 lb a.i./day enough to cover 500 acres (Haskell, 1996).
[d] Head includes face.
[e] "V" = "V" of the chest.
[f] Excluded a statistical outlier; the data from the chest dosimeter sample in the M/L replicate 2 was determined to be a statistical outlier, i.e., > 5 SDs (or > 99.99th percentile value) from the mean calculated without the outlier.
[g] Total exposure (µg/kg BW/lb a.i.) x 20 lb a.i. handled/day x 75.9 kg BW.
[h] Total exposure (µg/kg BW/lb a.i.) x 10 lb a.i. handled/day x 75.9 kg BW.

A.3 Flaggers

A flagger exposure study during aerial application of deltamethrin was not available. The exposure estimate for flaggers (Appendix B) was generated from the PHED (U.S. EPA, HWC, NACA, 1995). Some search criteria entered for flagger exposure were: type of pesticide -

insecticide; application method - applied by fixed-wing aircraft; clothing worn - short-sleeved shirt, long pants, and gloves. The exposure data were, thereafter, adjusted to reflect additional label required PPE, which are coveralls, chemical-resistant footwear plus socks, protective eyewear, and chemical-resistant head gear. A flagger is assumed to be exposed to diluted mix. According to the label short pants may be worn instead of long pants. Protective eyewear is assumed to provide minimal protection for dermal exposure. The coverage of surface area was assumed as follows: a short-sleeved shirt and short pants - 100% for the chest and back, 50% for upper arms and thighs; chemical-resistant headgear - 50% for the head. Exposure data generated from the PHED are shown in Appendix B. The exposure estimates for flaggers are shown in Table 5.

Exposure of handlers during aerial application of Decis® 1.5 EC was also estimated. Requirements for PPE for both products are the same. Therefore, the exposure estimates were adjusted to reflect a maximum application rate of 0.03 lb a.i./acre for Decis® 1.5 EC. Results are shown in Table 5.

Table 5. Estimated exposure of handlers to deltamethrin (Decis® 0.2 EC and 1.5 EC) from use in agriculture[a].

Work task	n	Exposure (μg/person/day) Dermal	Exposure (μg/person/day) Inhalation	ADD (μg/kg/day)	SADD (μg/kg/day)	AADD (μg/kg/day)	LADD (μg/kg/day)
Decis® 0.2 EC							
A. Agriculture: aerial application							
A.1 M/L[b]	16	310 ± 369	28.8 ± 12.1	0.46 ± 0.33	0.37	0.06	0.03
A.2 A[c]	16	268 ± 292	1.4 ± 0.5	0.25 ± 0.26	0.20	0.03	0.02
A.3 Flaggers[d]	11	30 (53)	1.2 (2.2)	0.03 (0.06)	0.03	0.005	0.002
Decis® 1.5 EC							
A. Agriculture: aerial application							
A.1 M/L[b]	16	465 ± 553	43.3 ± 18.2	0.70 ± 0.49	0.56	0.10	0.05
A.2 A[c]	16	402 ± 438	1.4 ± 0.7	0.36 ± 0.39	0.29	0.05	0.03
A.3 Flaggers[d]	11	44 (80)	1.8 (3.2)	0.05 (0.09)	0.04	0.007	0.004

n = number of replicates

[a] Years of employment = 40 years (default value), life expectancy = 75 years (Bureau of the Census, 1991).

[b] Exposure represents average ± SD. Assumed 50 workdays (Hoechst-Roussel, 1992) in a 62-day season (Meinders *et al*., 1991). Mixers/loaders wore long-sleeved coveralls (or long-sleeved shirts, long pants), shoes or boots, goggles, chemical-resistant gloves, and caps. These clothing and equipment are similar to those required by deltamethrin product label.

[c] Exposure represents average ± SD. Assumed 50 workdays (Hoechst-Roussel, 1992) in a 62-day season. Pilots wore long-sleeved flight suits (or long-sleeved shirts, long pants), shoes or boots, goggles, and fire-resistant gloves. These clothing and equipment are similar to those required by deltamethrin product label.

[d] The results represent average (highest) exposure rates. Assumed 50 workdays (Hoechst-Roussel, 1992) in a 62-day season (or a year). Flaggers were assumed to have worn coveralls, short-sleeved shirts, long pants, goggles, socks and shoes, and protective gloves. The highest exposure level represents the exposure to a flagging activity for an application of 900 acres per day (Haskell, 1996). The total amount of a.i. applied was 18 lb a.i. (0.02 lb a.i./acre x 900 acres = 18 lb a.i.)

B. Agriculture: groundboom application

Exposure estimates for mixer/loaders and applicators during groundboom application (Appendix B) were generated from the PHED (U.S. EPA, HWC, NACA, 1995). Some search criteria entered for mixer/loader exposure were: open system, insecticides containing less than two lb a.i. per gallon, clothing worn were long-sleeved shirt, long pants, and gloves. The exposure data were, thereafter, adjusted to reflect additional label PPE requirements, which are coveralls, chemical-resistant footwear plus socks, and a chemical-resistant apron. In addition, mixer/loaders are required to wear protective eyewear. Coverage of surface area for a chemical-resistant apron is assumed to be 75% for chest, back, thighs and legs. Protective eyewear is assumed to provide minimal protection for dermal exposure.

The exposure data generated from the PHED did not provide a standard deviation value. Consequently, the highest exposure level was estimated from the highest amount of a.i. a mixer/loader would handle per day. An applicator may treat an average of 50 acres per day (range 25-87 acres) (Haskell, 1996). The maximum application rate for Decis® 0.2 EC (0.2 lb a.i./gallon) is 0.02 lb a.i. per acre. Thus, an applicator may apply deltamethrin at an average of 1 lb a.i. (range 0.5 to 1.74) per day. A mixer/loader was assumed to provide services to two applicators. Therefore, a mixer/loader will mix/load twice as much the amount of a.i. an applicator would handle per day. Results are shown in Table 6.

Table 6. Estimated dermal and inhalation exposures of mixer/loaders and applicators to deltamethrin during groundboom application[a].

	Exposure (µg/person/day)		Absorbed dosage (µg/kg/day)			
	Dermal	Inhalation	ADD	SADD	AADD	LADD[d]
Decis® 0.2 EC (maximum label rate 0.02 lb a.i./acre)						
Mixer/loaders[b] (n=30)	289 (504)	25.7 (44.7)	0.42 (0.74)	0.14	0.02	0.01
Applicators[c] (n=86)	25 (43.4)	4.61 (8.02)	0.05 (0.09)	0.02	0.003	0.002
Decis® 1.5 EC (maximum label rate 0.03 lb a.i./acre)						
Mixer/loaders[b] (n=30)	434 (755)	38.5 (67.0)	0.64 (1.11)	0.21	0.03	0.02
Applicators[c] (n=86)	37.4 (65.1)	6.92 (12.0)	0.08 (0.14)	0.03	0.004	0.002

[a] Exposure data were generated from the PHED (U.S. EPA, HWC, NACA, 1995). Detailed exposure data are shown in Appendix A.

[b] Results, where applicable, represent average (highest) exposure estimates. Assumed 20 workdays (Meinders and Krieger, 1988) in a 62-day season (or a year). A mixer/loader was assumed to mix/load 2 lb a.i. (range 1.0 to 3.48) per workday.

[c] Results, where applicable, represent average (highest) exposure estimates. Assumed 20 workdays (Meinders and Krieger, 1988) in a 62-day season (or a year). An applicator was assumed to apply 1 lb a.i. (range 0.05 to 1.74) per workday.

[d] The worker is assumed to work 40 years in a 75-year life time.

Search criteria for applicator exposure from PHED were: liquid formulation, groundboom-tractor application, and clothing worn were short-sleeved shirt, long pants, and gloves. The applicators were assumed to be exposed to diluted mixtures. According to the label, short-sleeved shirt and short pants may be worn instead of long-sleeved shirt and long pants. Other label required PPE are coveralls, chemical-resistant footwear plus socks, protective eyewear and chemical-resistant headgear. Coverage of surface area is assumed as follows: a short-sleeved shirt and short pants - 100% for the chest and back, 50% for upper arms and thighs, chemical-resistant headgear - 50% for the head. Exposure estimates shown in Table 6 were adjusted to reflect these clothing requirements.

Exposure of handlers during groundboom application of Decis® 1.5 EC was also estimated. Requirements for PPE for both products are the same. Therefore, the exposure estimates were adjusted to reflect a maximum application rate of 0.03 lb a.i./acre for Decis® 1.5 EC. Results are shown in Table 6.

C. Cotton scouts

DFR of cotton treated with deltamethrin and surrogate transfer factors were used for the estimation of exposure of cotton scouts. It is assumed that cotton scouts (or pest control advisers) may enter treated fields to determine the effectiveness of pest control. The restricted entry interval as noted on the label is 12 hours post application. The exposure of cotton scouts to deltamethrin is assumed to have occurred at the end of 12 hours after an aerial or ground application, at which time the sprays have dried.

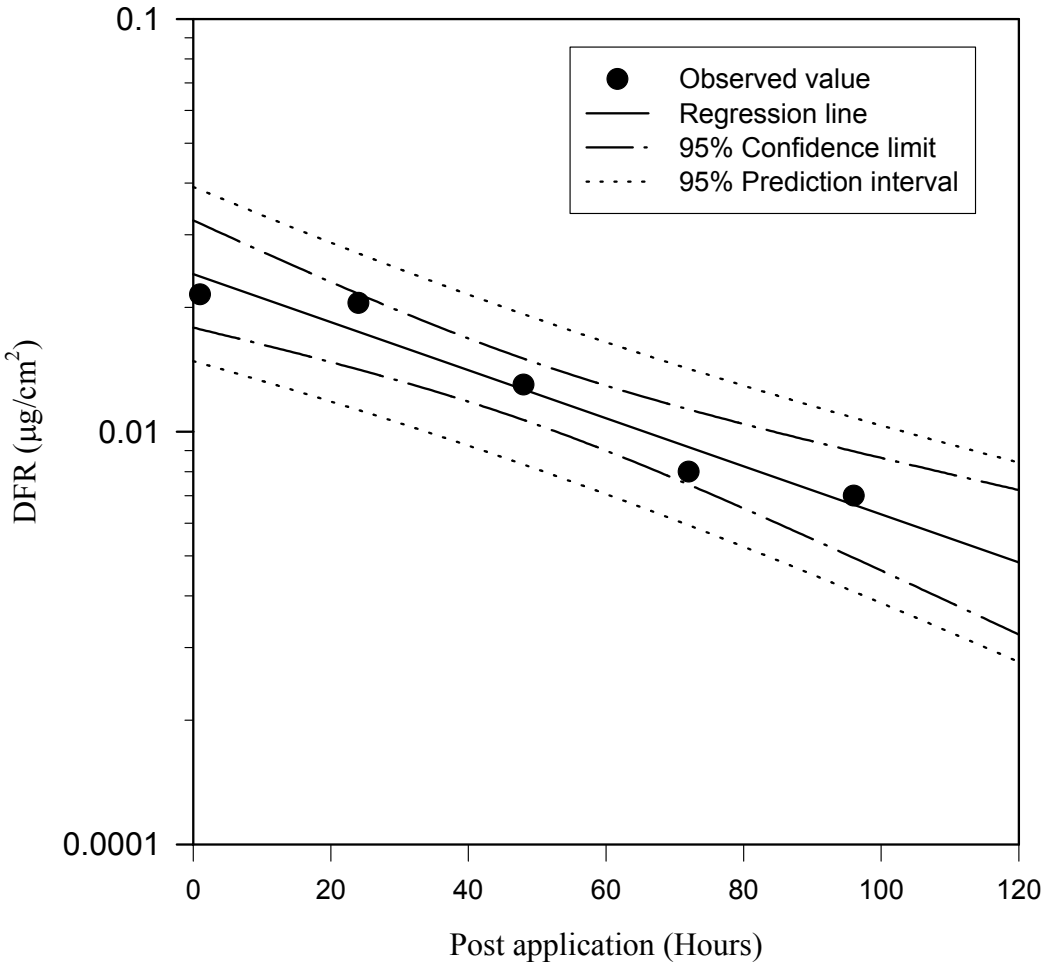
Deltamethrin DFR was obtained from a field study in Marana, Arizona (Estesen *et al*., 1979). The average height of cotton was 107 cm when plots were treated with deltamethrin (FMC 45498 or Decis®). Decis® was applied at a rate of 0.023 kg/ha (0.02 lb a.i./acre) using a manually drawn spray rig. It rained on the second (0.79 cm) and the fourth day (0.44 cm) post application. Leaf samples were collected at 0, 24, 48, 72 and 96 hours post application. Each sample consisted of samples from 100 leaves punched singly and consecutively from the top, middle and bottom portions of plants in all 4 rows, using 2.54-cm diameter leaf punches. A log-linear regression line (Figure 2) was constructed from field DFR data using the scientific graphing software SigmaPlot™ (Jandel Scientific, 1994a). The DFR data were also estimated for the 95% upper confidence limit. These DFR data have been adjusted to represent two sides of leaf surfaces. The correlation coefficient was 0.9727 indicating high correlation of data points. Rains did not seem to have any effect on the DFR data. The DFR data are shown in Table 7.

Table 7. DFR of deltamethrin on cotton based on one and two-sided leaf surfaces[a].

	DFR ($\mu g/cm^2$)	
Post application (days)	One-sided leaf surface	Two-sided leaf surfaces
0	0.043	0.0215
1	0.041	0.0205
2	0.026	0.013
3	0.016	0.008
4	0.014	0.007

[a] Application rate of Decis® = 0.02 lb a.i./acre.

Figure 2. Dissipation of deltamethrin dislodgeable foliar residues on cotton



95% Confidence limits - also called the confidence interval for a regression, describes the range where the regression line values will fall 95% of the time for repeated measurements (Jandel Scientific, 1994b).

95% Prediction interval - also called the confidence interval for the population, describes the range where the data values will fall 95% of the time for repeated measurements (Jandel Scientific, 1994b).

Potential dermal TFs were obtained from three studies conducted by Ware *et al*. (1973, 1974, 1975) in cotton using several pesticides. These studies were previously reviewed and the geometric mean potential dermal TFs were reported for hand (950 cm^2/hr), upper body (1,020 cm^2/hr) and lower body (9,640 cm^2/hr) (Dong *et al.*, 1991). The product label does not specify clothing requirements for cotton scouts entering a treated field after the expiration of the restricted entry interval. Cotton scouts are assumed to be wearing work clothing (long-sleeved

shirts, long pants, socks and shoes) with or without gloves. The exposure period for a cotton scout to treated foliage was assumed to be 6 hours per workday. A cotton scout is expected to spend more than two hours traveling between fields during a workday. In addition, not all cotton fields are expected to be treated with deltamethrin. This will also reduce the exposure time of a cotton scout to deltamethrin foliar residues. Results of the exposure estimates for hands, upper body, and lower body are shown in Table 8. Total exposure of a cotton scout based on protected and unprotected hands are summarized in Table 9.

Cotton scouts are assumed to have been exposed to deltamethrin for 40 days in a 62-day season of use (or in a year). This is based on the assumption that when deltamethrin is available commercially, not all cotton fields will be treated with this chemical. Absorbed dosages for short- and long-term exposures are shown in Table 9.

Exposure of cotton scouts who enter fields treated with Decis® 1.5 EC was also estimated. Requirements for PPE for both products are the same. Therefore, the exposure estimates were adjusted to reflect a maximum label rate of 0.03 lb a.i./acre for Decis® 1.5 EC. Results are shown in Table 9.

II. Use of deltamethrin in residential, industrial and institutional pest controls

K-Othrine® SC (4.75% by weight) is recommended for use by pest control operators and/or commercial applicators to control pests in and around residential, industrial and institutional structures, and on various modes of transportation. Permitted areas of use include houses, laboratories, apartments, and non-food areas of schools, trucks, hotels, aircraft, restaurants, and railcars. Exposure of mixer/loader/applicators or pest control operators (PCOs) was derived from a study performed in Zagreb, Yugoslavia in 1980 (Kozar *et a*l., 1981). Estimation of home occupants (infants and adults) were based on a dislodgeable residue study of deltamethrin following a broadcast application (Maxey *et al.*, 1995). It was assumed that people who resided or worked in other treated areas would not experience higher exposure than home occupants because the exposure estimates were based upon maximum label rate, exposure was assumed to occur shortly after an application, and dermal contact was continued up to 6 hours in duration.

The specimen label for K-Othrine® SC does not specify clothing requirements for pest control operators. In this exposure estimate, workers are assumed to be wearing long-sleeved shirt, long pants, chemical-resistant gloves, and shoes plus socks. The application of K-Othrine® SC can be repeated at 21-day intervals or as necessary to maintain adequate control. However, it is unlikely that a PCO will make scheduled applications every month for home owners or industrial settings. In an extreme case, it is assumed that a PCO will make five scheduled applications to the same home or other institutional setting.

Default factors used in the estimation of exposures for infants are: body weight = 10.2 kg (ICRP, 1974), inhalation volume = 1.51 m^3/6 hrs during active play (4.2 L/min (ICRP, 1974) x 60 min/hr x 6 hrs x 1 m^3/1,000 L). For the rest period, inhalation volume = 1.62 m^3/18 hrs during rest period (1.5 L/min (ICRP, 1974) x 60 min/hr x 18 hrs x 1 m^3/1,000 L).

Table 8. Deltamethrin dislodgeable foliar residues of cotton and the estimated dermal exposure of cotton scouts[a].

A. Average exposure[b]

Post appl. (days)	DFR (μg/cm^2) (0.02 lb a.i./acre)	Dermal exposure (μg/person/day)[c]					
		Hands				Total dermal exposure	
		With gloves	No gloves	Upper body	Lower body	With gloves	No gloves
0.5	0.0205	11.69	116.9	12.55	118.6	142.8	248.0
1	0.0175	9.98	99.75	10.71	101.2	121.91	211.7
2	0.0125	7.24	72.39	7.77	73.46	88.47	153.6
3	0.0092	5.24	52.44	5.63	53.21	64.09	111.3
4	0.0067	3.82	38.19	4.10	38.75	46.67	81.04
5	0.0048	2.74	27.36	2.94	27.76	33.44	58.06

B. Upper 95% prediction limits[d]

Post appl. (days)	DFR (μg/cm^2) (0.02 lb a.i./acre)	Dermal exposure (μg/person/day)[c]					
		Hands				Total dermal exposure	
		With gloves	No gloves	Upper body	Lower body	With gloves	No gloves
0.5	0.0274	15.62	156.2	16.77	158.5	190.9	331.4
1	0.0223	12.71	127.1	13.65	129.0	155.3	269.7
2	0.0154	8.78	87.78	9.42	89.07	107.3	186.3
3	0.0117	6.67	66.69	7.16	67.67	81.5	141.5
4	0.0094	5.36	53.58	5.75	54.37	65.48	113.7
5	0.0077	4.39	43.89	4.71	44.54	53.64	93.1

[a] Application rate of deltamethrin = 0.02 lb a.i./acre. DFR data were based on two sides of leaf surfaces. Exposure estimates were based on 6 hours per workday. Cotton scouts are assumed to be wearing long-sleeved shirts, long pants, socks and shoes, and gloves (or no gloves).

[b] DFR data were determined from a regression line using SigmaPlot™ (Jandel Scientific, 1994a).

[c] Geometric mean potential dermal transfer factors (cm^2/hr) are: hands = 950, upper body = 1,020, lower body = 9,640. Cotton gloves provide 90% exposure protection for hands of scouts (Aprea *et al*., 1994).

[d] Obtained from the regression analysis using SigmaPlot™ (Jandel Scientific, 1994a).

Table 9. Estimated exposure of cotton scouts to deltamethrin 0.2 EC and 1.5 EC [a].

Work task	Exposure (μg/person/day) Dermal	Inhalation	ADD (μg/kg/day)	SADD (μg/kg/day)	AADD (μg/kg/day)	LADD (μg/kg/day)
Deltamethrin 0.2 EC						
Cotton scouts (gloved hands) [b]	143 (191)	negligible	0.13 (0.17)	0.08	0.01	0.01
(no gloves) [b]	248 (331)	negligible	0.22 (0.29)	0.14	0.02	0.01
Deltamethrin 1.5 EC						
Cotton scouts (gloved hands) [b]	214 (286)	negligible	0.19 (0.25)	0.12	0.02	0.01
(no gloves) [b]	372 (497)	negligible	0.33 (0.44)	0.21	0.04	0.02

[a] Years of employment = 40 years (default value), life expectancy = 75 years (Bureau of the Census, 1991).
[b] The results represent average (upper 95% confidence limits). Cotton scouts were assumed to be working 6 hours per workday and 40 days (Meinders and Krieger, 1988) in a 62-day use season (or in a year).

A.1 Exposure of pest control operators.

A field exposure study of workers to deltamethrin was conducted in Zagreb, Yugoslavia in 1980 (Kozar *et al*, 1981). Decis® 2.5 EC was applied at a rate of 15 mg/m^2 by four workers to control houseflies indoors (animal houses, stores, parts of restaurants and hotels, etc.), and outdoors (around animal houses, and waste disposal sites). A general maximum application rate for K-Othrine® SC is 23.3 mg/m^2. The final exposure estimates were adjusted to reflect this application rate. The spray operation was designed to last two consecutive weeks. The workers worked for six consecutive days. After a day off, they worked for five days in the second week. Spraymen used a motor sprayer (Solo) that produced a droplet size of 50 μm and conventional sprayers (Bertaud) which produced a droplet size of 200 μm at a pressure of 2 atm. The spraymen worked as a team of two when utilizing either sprayer. The two workers in a team alternately performed the task as a mixer and a serviceman or as an applicator. For the mixing process, the preweighed insecticide (300 gm) was transferred into a sprayer to which 300 gm of sugar was added and then filled-up to 10 liters with water. When using motorized sprayers for outdoor pest control, spraymen wore daily washed overalls, a cap with a shield, plastic transparent face shield, disposable filter paper dust masks (3M product), rubber gloves and canvas ankle shoes. For indoor application using conventional sprayers, the applicators wore coats, rubber gloves and disposable masks.

On the fourth day of the deltamethrin application, exposure of four workers was monitored using exposure pads (4.0 cm x 2.5 cm). The study protocol followed that of WHO/VBC. These pads, which were provided by WHO/VBC/PDS, were placed at these regions: forehead, left side of the chest, left arm, left forearm, left leg, and left lower leg. The number of charges sprayed were 51 for motorized sprayers and five for conventional sprayers. Analysis of samples was done by the Laboratory for Analytical Chemistry of the Institute for Plant Protection in Zagreb. Neither QA statement nor field spike recovery was mentioned in the report. However, these are the only submitted exposure data for deltamethrin for PCOs. Therefore, these data were used instead of any other surrogate data. Results of the exposure study and estimation of exposure are shown in Table 10. These pad residues were used to determine dermal exposure of PCOs. The exposure time per day for a PCO is 6 hours. The PCO is expected to spend more than two hours traveling from place to place in a workday. Results of the exposure estimates are shown in Table 11.

All four spraymen experienced temporary itching and burning on the face after removing the respiratory (paper) masks. Two spraymen complained of nasal hypersecretion. However, these spraymen continued to apply deltamethrin thereafter.

Table 10. Pad residues of deltamethrin from the study in Zagreb, Yugoslavia in 1979.

		Pad residues (μg/10 cm^2)			
Location[a]	spraymen	1	2	3	4
Forehead		17	19	12	11
Chest		32	51	26	21
Arm		25	33	19	24
Forearm		152	98	102	88
Leg		310	315	274	219
Lower leg		445	460	375	257

[a] Representation of exposure residues for exposure estimation: forehead for head, face, back and front of neck; chest for chest/stomach; arm for upper arms and back; forearm for forearms and hands; leg for thighs; lower leg for lower legs and feet.

Inhalation of deltamethrin during a pest control operation in Zagreb was not properly monitored. Residues found on paper masks worn by the sprayers were not appropriate to be used to estimate inhalation exposure because air flow rate was not measured. Further, residues on the masks could not be determined as to how much would contribute to inhalation exposure. Therefore, inhalation exposure from an application of chlorpyrifos for termite control (Fenske and Elkner, 1990) was used as a surrogate. Applications in this study were made around the exterior and interior perimeter of structures. Three different injection devices were used for applications. Injection of crawl spaces were also made. The selection of this surrogate inhalation exposure data was based on similarity of chlorpyrifos and deltamethrin regarding formulation and the use in pest control. Inhalation exposure to chlorpyrifos was 0.06 ± 0.04 mg/hr. The estimate was based on an application of 1% chlorpyrifos solution and an inhalation rate of 1,740 L/hr. Thus, inhalation exposure was adjusted to reflect the deltamethrin application rate of 0.06% solution and an inhalation rate of 840 L/hr for moderate work activity (U.S. EPA, 1985). The adjusted inhalation exposure was 0.010 ± 0.007 mg/6-hr day.

Table 11. Estimated exposure of mixer/loader/applicators or pest control operators to deltamethrin during indoor and outdoor pest control operation.

	Exposure (mg/person/day)		Exposure (µg/kg/day)		
	Dermal	Inhalation	ADD	AADD[a]	LADD[b]
Mean	48.8	0.010	43.2	26.4	14.1
SD	10.0	0.007	8.9		

[a] Mixer/loader/applicators were assumed to be wearing long-sleeved coveralls (or long-sleeved shirts, long pants), shoes or boots, chemical-resistant gloves. The number of workdays per year is 223 days (Munro, 1992).
[b] Based on 40 years of work in a 75-year lifetime.

A.2 Exposure of infants to deltamethrin residues in treated homes.

DowElanco conducted a study to determine dislodgeable residues (DR) of deltamethrin on treated carpet (Maxey *et al*., 1995). This study was conducted in compliance with Good Laboratory Practice standards (40 CFR Part 160). Method and field spike recoveries were also conducted to determine the efficiency of extraction method and analysis, and handling of field samples. The carpet in a single private dwelling was sprayed with deltamethrin mixture (Suspend SC, 0.06%) at a rate of one gallon per 800 ft^2 (2.84 mg/ft^2 or 3.06 $\mu g/cm^2$) using a hand-held sprayer, equipped with tank and nozzle pressure regulators. Initial residue deposit of deltamethrin was determined by placing coupons made with denim patch backed with aluminum foil. These samples were collected immediately after the application.

Dislodgeable residues of deltamethrin on the carpet were collected on a denim coupon (4" x 4") affixed at the bottom of a weighted block or "Dow Sled" (8.5-lb weight, 9-in^2 block), which gave a pressure of approximately 0.9 lb/in^2. The Dow Sled was dragged across each of the treated lanes. The pressure exerted by a walking child is approximately 22.5 lb/25 in^2 (bottom of two feet), or 0.9 lb/in^2. The pressure exerted by a crawling child is approximately 0.94 lb/in^2 (22.5 lb/24 in^2 (two knees and two hands)). The area of the treated room was divided into 16 dragged lanes of 3" x 48" each. The Dow Sled was dragged across each of the treated lanes. Sample collection times were pre-application, 0 (right after finish application), 1, 2, 3, 4, 5, 6, 8, 12, 24, 48, 72, 96, 120, 240 and 504 hours post application. Results are shown in Table 12.

Table 12. Dislodgeable residues and transfer coefficients for deltamethrin following a broadcast application of Suspend SC (0.06%) on a carpeted surface[a].

Sampling post application (hr)	Dislodgeable residues[b] (mean, μg/ft^2)	Transfer coefficient[c] (%)
Pre-	--	--
0	521	21.5
1	107	4.42
2	92.2	3.81
3	78.6	3.25
4	69.2	2.86
5	73.4	3.03
6	72.4	2.99
8	59.0	2.44
12	61.8	2.55
24	57.3	2.37
48	61.2	2.53
72	61.4	2.54
96	66.9	2.76
120	66.0	2.73
240	57.1	2.36
504	65.1	2.69

[a] The treatment rate was approximately 1 gallon of mixture (0.06%) per 800 ft^2. This represented a maximum label rate of 2.84 mg/ft^2 (or 3.06 μg/cm^2).
[b] From 4 quadrants and were corrected for field spike recoveries (high spike at 57.2 μg, mean recovery = 81.5%). Dislodgeable residues were not corrected for method recovery due to a recovery of 110%.
[c] (mean DR x 100)/initial deposit of 2,420 μg/ft^2 (or 2.61 μg/cm^2 x 929 cm^2/ft^2).

Dermal and Oral Exposure of Infants to Deltamethrin
Dermal exposure:

A mean DR of 92.6 ± 14.2 μg/ft^2, obtained between 1 and 3 hours post application, was used in the estimation of exposure. It was assumed that home occupants would enter a treated home after a brief ventilation period. Exposure of infants via dermal and oral routes to deltamethrin was estimated based on the mean DR.

An equilibrium model proposed by Durkin *et al*. (1995) was employed to estimate dermal exposure of infants and adults. This model was derived from field DFR and dermal hand exposure. DR was used in place of DFR in the model since DR is also the source of dermal exposure like DFR, especially for home occupants. The modified model used for the estimation of dermal exposure is shown below.

$$\log TR = 1.09 \log DR + 0.05$$

(Notes: TR = transfer rate (μg/(cm^2.hr) and DR = dislodgeable residue (μg/cm^2)

$$\log TR = 1.09 \log 92.6 + 0.05$$
$$TR = 0.091 \text{ (μg/(cm}^2\text{.hr)}$$

Dermal exposure is simply the result of calculated transfer rate x surface area of body regions that will come in contact with residues x number of hours an infant may be exposed to deltamethrin in a treated area. It was assumed that 75% of the body surface area may be exposed

to residues on the treated surface. A daily 6-hour activity and 18-hour rest period for a one-year old infant was assumed (Ross *et al.*, 1992). The body weight is 10.2 kg and the surface area is 3,925 cm^2 (ICRP, 1974). Dermal exposure was estimated as follows:

Dermal exposure = 0.091 (μg/(cm^2.hr) x 6 hours/day x 75% (3,925 cm^2) ÷ 10.2 kg = 157 μg/kg/day
ADD = 157 x 6.7% = 10.52 μg/kg/day

Oral exposure:

Oral exposure was calculated based on the surrogate transfer of 474 μg of chlorpyrifos hand residue from 43.1 ft^2 (Thongsinthusak, 1995). This hand residue was adjusted to reflect the hand size of an infant (1/4 of adult), use rate, ingestion rate and possible contacted surface area of 40 ft^2. Oral absorption of deltamethrin was estimated to be 58% (Frank, 1996). Calculation of oral dose is shown below.

474 μg (hand residue) x 2,160 μg/ft^2 x 0.25 (hand size ratio) x 40 ft^2 (contact area) x 0.5 (ingestion rate)
43.1 ft^2 11,828 μg/ft^2 x 10.2 kg BW
Oral exposure = 0.98 μg/kg/day
Oral ADD = 0.98 x 0.58 = 0.57 μg/kg/day
(Note: Application rates: deltamethrin = 2,160 μg/ft^2, chlorpyrifos = 11,828 μg/ft^2.

Average for dermal and oral ADD = 10.52 + 0.57 = 11.09 μg/kg/day
SD for dermal and oral ADD = 1.34 + 0.20 = 1.54 μg/kg/day

A calculation procedure for standard deviations is similar to that used to calculate the average value. Results are shown in Table 13.

A number of exposure days for infants who reside in homes treated with deltamethrin by PCOs was estimated as follows: assumed a maximum number of deltamethrin applications per year (two each during summer and spring, and one in fall) equaling 5. The product label indicates that applications may be done at 21-day intervals or as necessary. It is unlikely that re-infestation of pests in a home would occur in a short period of time after each pest control application.

An exposure period to a high level of surface residues for each application would occur within 3 hours post application and continue for about three days. The product label does not indicate a reentry interval. Aeration of the home may possibly last only a brief period of time. Loss of dislodgeable residues appears to be due to redistribution on the surface. An estimated total number of exposure days per year to high levels of deltamethrin DR = 3 x 5 = 15 days.

Inhalation exposure:

Data on inhalation exposure of infants to deltamethrin while playing in a treated room were not available. Ambient air monitoring conducted in rooms treated with chlorpyrifos was used as a surrogate. This is because chlorpyrifos and deltamethrin have similar formulation and use environment. Maximum air concentration of chlorpyrifos as a 4-hour time-weighted average (TWA) was 15.35 μg/m^3. This period is assumed to be an active period for infants. For the rest period, air concentration of chlorpyrifos averaged from 8, 12, and 24 hour-TWA, which was 9.46 μg/m^3 (Thongsinthusak *et al.*, 1993b). In order to estimate air concentration for deltamethrin from chlorpyrifos data, an adjustment is needed with respect to vapor pressure and molecular weight of the two compounds. Available data on the molecular diffusion coefficient of organic vapors in air suggested that the rate of loss is proportional to a compound's vapor pressure and

the square root of its molecular weight (Hartley, 1969). Therefore, the rate of loss for chlorpyrifos and deltamethrin, and application rates were factored in for the estimation of deltamethrin inhalation exposure.

Chlorpyrifos: vp = 1.87×10^{-5} mmHg, MW = 350.58

$$\text{Rate of loss} = 1.87 \times 10^{-5} \times \sqrt{350.58}$$
$$= 3.5 \times 10^{-4}$$

Deltamethrin: vp = 1.5×10^{-8} mmHg, MW = 505.22

$$\text{Rate of loss} = 1.5 \times 10^{-8} \times \sqrt{505.22}$$
$$= 3.4 \times 10^{-7}$$

Ratio of rate of loss: chlorpyrifos/deltamethrin = $3.5 \times 10^{-4} / 3.4 \times 10^{-7} = 1 \times 10^{3}$.

<u>During active period:</u>

air concentration $= 15.35\ \mu g/m^3 \times \frac{2{,}160\ \mu g/ft^2}{11{,}828\ \mu g/ft^2} \times \frac{1}{10^3}$
$= 2.8 \times 10^{-3}\ \mu g/m^3$

inhalation exposure $= \frac{2.8 \times 10^{-3}\ \mu g/m^3 \times 1.51\ m^3}{10.2\ kg}$
$= 0.0004\ \mu g/kg$

Note: Inhalation rate of a one-year old child: active period = 4.2 L/min or 1.51 m^3/6 hours; rest period = 1.62 L/min or 1.44 m^3/18 hours.

<u>During rest period</u>

air concentration $= 9.46\ \mu g/m^3 \times \frac{2{,}160\ \mu g/ft^2}{11{,}828\ \mu g/ft^2} \times \frac{1}{10^3}$
$= 1.73 \times 10^{-3}\ \mu g/m^3$

inhalation exposure $= \frac{1.73 \times 10^{-3}\ \mu g/m^3 \times 1.62\ m^3}{10.2\ kg}$
$= 0.0003\ \mu g/kg$

Total inhalation exposure: $= 0.0004 + 0.0003 = 0.0007\ \mu g/kg/day$
Total absorbed inhalation exposure $= 0.0007 \times 0.5 = 0.0004\ \mu g/kg/day$

<u>Dermal and Oral Exposure of Adult Males to Deltamethrin</u>
<u>Dermal exposure</u>:

Dermal exposure of adult males to deltamethrin dislodgeable residues was estimated based upon the procedure employed for infants. It was assumed that 75% of the body surface area may be exposed to residues on the treated surface. A daily activity period of 6 hours for infants was also employed to estimate dermal exposure assuming that an adult had to stay in close contact with an infant. The body weight is 75.9 kg and the surface area is 19,400 cm^2 (Thongsinthusak *et al*., 1993a). Dermal exposure was estimated as follows:

Dermal exposure = 0.091 ($\mu g/(cm^2.hr)$ x 6 hours/day x 75% (19,400 cm^2) ÷ 75.9 kg = 105 $\mu g/kg/day$

ADD = 105 x 6.7% = 7.04 μg/kg/day

Oral exposure:

Oral exposure was calculated based on the transfer of 474 μg of hand residue from 43.1 ft^2 (Thongsinthusak, 1995). This hand residue was adjusted to reflect ingestion rate, use rate and possible contact surface area of 80 ft^2. A mean oral absorption of deltamethrin was estimated to be 58.4% (Frank, 1996). This estimate was based on a study employing tralomethrin in SD rats (Tanoue, 1988). Calculation of oral dose for adult males is shown below.

$$\frac{474\ \mu g\ \text{(hand residue)}}{43.1\ ft^2} \times \frac{2{,}160\ \mu g/ft^2}{11{,}828\ \mu g/ft^2} \times \frac{80\ ft^2\ \text{(contact area)}}{75.9\ kg\ BW} \times 0.05\ \text{(ingestion rate)}$$

Oral exposure = 0.11 μg/kg/day
Oral ADD = 0.11 x 0.58 = 0.06 μg/kg/day

Average for dermal and oral ADD = 7.04 + 0.06 = 7.10 μg/kg/day
SD for dermal and oral ADD = 0.94 + 0.02 = 0.96 μg/kg/day

A calculation procedure for standard deviations was similar to that used to calculate the average value. Dermal and oral exposure of adult males is similar to that of adult females. Therefore, a separate data set is not presented. A number of annual exposure days for adults who reside in homes treated with deltamethrin by PCOs were assumed to be the same as that for infants. Results are summarized in Table 13.

Inhalation exposure:

Inhalation exposure of adults to deltamethrin while residing/playing in a treated room was estimated similarly to that for infants. Inhalation exposure during active and rest periods was calculated as follows:

During active period:

air concentration $= 15.35\ \mu g/m^3 \times \frac{2{,}160\ \mu g/ft^2}{11{,}828\ \mu g/ft^2} \times \frac{1}{10^3}$
$= 2.8 \times 10^{-3}\ \mu g/m^3$

inhalation exposure $= \frac{2.8 \times 10^{-3}\ \mu g/m^3 \times 5.04\ m^3}{75.9\ kg}$
$= 0.00019\ \mu g/kg$

Note: Inhalation rate of an adult male: active period = 14 L/min or 5.04 m^3/6 hours, rest period = 12 L/min or 13.0 m^3/18 hours

Rest period
air concentration $= 9.46\ \mu g/m^3 \times \frac{2{,}160\ \mu g/ft^2}{11{,}828\ \mu g/ft^2} \times \frac{1}{10^3}$
$= 1.73 \times 10^{-3}\ \mu g/m^3$

inhalation exposure $= \frac{1.73 \times 10^{-3}\ \mu g/m^3 \times 13.0\ m^3}{75.9\ kg}$
$= 0.0003\ \mu g/kg$

Total inhalation exposure: = 0.00019 + 0.0003 = 0.0005 μg/kg/day
Total absorbed inhalation exposure = 0.0005 x 0.5 = 0.0003 μg/kg/day

The exposure estimates for PCOs and home residents were based solely on the application of K-Othrine® SC (4.75%), not K-Othrine® Dust (0.05%). The recommended application rate for K-Othrine® SC is 2.16 gm/1,000 ft^2, which is 19-fold higher than that for K-Othrine® Dust (0.113 g/1,000 ft^2. Furthermore, the label for K-Othrine® Dust stipulates that application of this product in living space should be done in such a manner as to avoid deposition on exposed surfaces or introducing the material into the air. Application of K-Othrine® SC can be done directly on rugs and carpets where residual contact by residents is substantial. Therefore, exposure to deltamethrin in homes treated with K-Othrine® SC would represent an extreme case scenario.

There were no deltamethrin exposure studies for its use in aircrafts, hospitals, hotels/motels, restaurants, schools, theaters, etc. Potential contact with residues or inhalation exposure to deltamethrin may occur. It was assumed that an application of deltamethrin products will be performed in the absence of people in the area. The exposure of the people to deltamethrin would occur through dermal contact with residues, inhalation of airborne residues or ingestion of contaminated food. It is unlikely that the exposure of adults or children would be higher for these other use scenarios than infants or adults who reside and play in a room treated with K-Othrine® SC.

III. Application of K-Othrine® Dust (0.05%) to control pests in flowers and ornamentals.

According to the product label, K-Othrine® Dust may be used to control pests on shrubs and ornamental plants. Since there were no chemical-specific exposure data available, surrogate exposure data were obtained from the application of the dustable powders zineb and thiram in greenhouses (Brouwer, 1992). The application rates for these fungicides were about 100 and 75 gm a.i./1,000 m^2, respectively. The application rate of deltamethrin is 113 mg/1,000 ft^2 (8 ounces of K-Othrine® Dust per 1,000 ft^2) or 1.22 gm a.i./1,000 m^2.

The applicator exposure study for dustable powders zineb and thiram was conducted in glass-covered greenhouses in the Netherlands. The dermal exposure monitoring was done to the hands and forearms (surface area = 740 cm^2) by the use of prewashed long-sleeved cotton gloves. Respiratory exposure was carried out by the use of an IOM personal air sampler with a Millipore mixed cellulose ester filter (25 mm, pore diameter 8 μm) attached to a constant-flow air-sampling pump operated at a flow rate of 2 L/min. The dustable powder was loaded directly into the tank. In a few cases the powder was scooped or poured into a vessel and weighed subsequently. Dusting was performed with a knapsack dust blower for an average of about 7 minutes per 1,000 m^2. The dusting was performed mainly in the evening with the windows closed.

The surrogate exposure data were adjusted to reflect the deltamethrin application rate. It is likely that hand exposure obtained from the use of a cotton dosimeter are higher than that from handwashes (Smith *et al*., 1991). In order to compensate for limited surface areas being monitored, surrogate data were not adjusted for this potential overestimation. Table 14 shows exposure of applicators during the application of deltamethrin dust to ornamental plants.

Table 13. Estimated exposure of infants and adults to deltamethrin dislodgeable residues on treated surfaces[a].

Work task	Exposure (μg/person/day) Dermal	Oral	Inhalation	ADD (μg/kg/day)	AADD (μg/kg/day)	LADD (μg/kg/day)
Infants (residual contact)[b]	1,601 ± 204	10.04 ± 3.47	0.007	11.09 ± 1.54	0.46	N/A
Adult males (residual contact)[c]	7,970 ± 1,063	8.03 ± 2.78	0.038	7.10 ± 0.96	0.29	0.16

[a] The following factors were used in the estimation of exposures: infant body weight = 10.2 kg (ICRP, 1975). Data represent average ± SD. N/A = not applicable

[b] The number of days exposed per year for infants was assumed to be 15 days (5 applications/year x 3 days of high exposure level/application). LADD for infants was not estimated because the level of exposure will be changed as they are older. Infants were assumed to be wearing diapers.

[c] The number of days exposed per year for adults was assumed to be 15 days (3 applications/year x 5 days of high exposure /application). Years of living in deltamethrin treated home = 40 years. Life expectancy = 75 years (Bureau of the Census, 1991). Adults were assumed to be wearing minimal clothing.

Table 14. Estimated exposure of workers to deltamethrin during application of K-Othrine® Dust (0.05%) to flowers and ornamentals[a].

	Unadjusted surrogate exposure[b] (mg/person/day) Potential dermal	Inhalation	Adjusted deltamethrin exposure[c] (mg/person/day) Dermal	Inhalation	ADD (μg/kg/day)	SADD[d] (μg/kg/day)	AADD[e] (μg/kg/day)	LADD (μg/kg/day)
Loader/Applicator[b] (n = 10)	315	4.50	0.438	0.063	0.80	0.13	0.07	0.04

[a] Workers were assumed to be wearing long-sleeved shirts, long pants, shoes plus socks, and rubber gloves. Results represent geometric mean values. GSD could not be determined because individual data were not available from the published article.

[b] Average application rate was 8,128 mg a.i./1,000 ft^2. Inhalation rate per 8-hour workday = 6.72 m^3 (14 L/min x 60 min x 8 hours).

[c] The exposure was adjusted to reflect an application rate of deltamethrin at 113 mg a.i./1,000 ft^2 for use in flowers and ornamentals.

[d] Assume 15 workdays in a 90-day season. The product label indicates deltamethrin can be applied as soon as the insects appear and repeated at 7-day intervals or as long as insects continue to appear.

[e] Assume 30 workdays in a year.

EXPOSURE APPRAISAL

The exposure estimates presented in this document were derived from studies using deltamethrin and surrogate studies using other pesticides. Any appropriate deltamethrin exposure studies submitted by the registrants would take precedence over generic sources. Defaults for physiologic factors employed in the calculation, e.g., body weights, body surface areas and inhalation rates were originally taken from one source at the 50th percentile to maintain consistency. Actual physiologic values, if available, were used rather than the defaults.

There is convincing evidence that extrapolation of exposure from a short monitoring period would contribute to overestimation of exposure. A study by Spencer *et al*. (1995) showed that if a full day's exposure was extrapolated from a 1/3 workday monitoring period, the exposure would be overestimated by 50-80% and from a 1/2 workday, 20-40%. Examples of approximate monitoring periods (minutes) for various studies used in this document were: mixer/loaders (aerial application) - 30; applicators (aerial application) - 30; pest control operators (PCO) - not explicitly specified, but was assumed 360. Some of these monitoring periods are below 1/3 of a workday or 160 minutes. It is apparent that extrapolation of exposure to a full workday or 8 hours from a short exposure monitoring period would likely overestimate exposure by 50-80%.

The exposure estimation for cotton scouts, applicators of dust formulation to ornamentals, and adults and children playing in treated homes were derived mainly from surrogate data. It was assumed that deltamethrin exposure would be proportional to surrogate pesticides based upon application rates, monitoring periods, efficiency of residue transfer and vapor pressure. The assumption may not be always true. An exposure study using deltamethrin and an appropriate monitoring period would be ideal.

A review of dermal absorption of pesticides and other chemicals revealed that dermal absorption of these chemicals in rats and other animals is generally greater than that in humans (Thongsinthusak, 1991). A dermal absorption value of 6.7% for deltamethrin, which was obtained from a rat study, is likely to overestimate the dermal absorption in humans.

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Acknowledgment:

For consistency in the preparation of risk characterization and exposure assessment documents, sections on Physical and Chemical Properties, Regulatory History, Technical and Product Formulations, Usage, and Pharmacokinetics/Animal Metabolism were provided by J. P. Frank, Staff Toxicologist, of the Medical Toxicology Branch, DPR. The section on Technical and Product Formulations was modified by eliminating some redundant information that appears in the Label Precautions section. The Worker Illnesses section was adopted from the Risk Characterization Document because deltamethrin has not been used in California.

Appendix A
Dermal Absorption of Deltamethrin in Male Rats
(Tables A.1 - A.3)

Table A1. Percent recovery of administered dose of deltamethrin.

		Percent of administered dose (mean)									
Dose	Sacrifice time (hours)	Unabsorbed dose-(a)	Treat skin site-(b)	Blood	Carcass	CW/CW	Urine	Feces	Total recovery	Dermal absorption-(c)	Adjusted dermal abs-(d)
Group 4	0.5	86.35	16.4	0	0.05	0	0.005	0.03	102	16.49	16.16
136 ug/cm2	1	89.01	17	0	0.07	0	0.005	0.005	106	17.08	16.11
(1.7 mg/animal)	2	101.875	5.5	0	0	0	0.01	0.005	108	5.52	5.11
	4	92.53	12.9	0	0	0	0.03	0.01	105	12.94	12.32
	10	96.23	9.28	0.01	0.16	0.03	0.17	0	105	9.65	9.19
	24	96.07	6.89	0.01	0.33	0.15	0.32	0.07	103	7.77	7.54
	120	96.2	5.05	0	0.08	0.51	1.75	0.66	104	8.05	7.74

CW/CW - cage wash/cage wipe

(a) sum of the percent dose recovered from the non-occlusive cover, enclosure rinse, skin wash.

(b) washed at each sacrifice time, except for the 24 and 120-hour sacrifice times where washing was done 10 hours post dosing.

(c) sum of percent dose recovered in the treated skin site, blood, carcass, CW/CW, urine, feces.

(d) "(c)" was adjusted to reflect a 100% recovery of the administered dose.

		Percent of administered dose (mean)									
Dose	Sacrifice time (hours)	dose-(a)	Treat skin site-(b)	Blood	Carcass	CW/CW	Urine	Feces	Total recovery	Dermal absorption-(c)	Adjusted dermal abs-(d)
Group 5	0.5	88.34	10.8	0	0	0	0.005	0	99.1	10.81	10.90
44 ug/cm2	1	87.33	6.35	0	0	0	0.005	0.005	93.7	6.36	6.79
(0.551 mg/animal)	2	97.34	5.96	0	0	0	0.02	0	103	5.98	5.81
	4	90.17	4.13	0	0.44	0.01	0.04	0	94.8	4.62	4.87
	10	99.64	6.35	0.01	0.28	0.11	0.21	0	106	6.96	6.57
	24	98.62	13.1	0.01	0.35	0.18	0.63	0.11	113	14.38	12.73
	120	90.11	4.18	0	0.15	1.12	2.07	1.05	98.7	8.57	8.68

CW/CW - cage wash/cage wipe

(a) sum of the percent dose recovered from the non-occlusive cover, enclosure rinse, skin wash.

(b) washed at each sacrifice time, except for the 24 and 120-hour sacrifice times where washing was done 10 hours post dosing.

(c) sum of percent dose recovered in the treated skin site, blood, carcass, CW/CW, urine, feces.

(d) "(c)" was adjusted to reflect a 100% recovery of the administered dose.

Table A1 (cont.). Percent recovery of administered dose of deltamethrin.

		Percent of administered dose (mean)									
Dose	Sacrifice time (hours)	Unabsorbed dose-(a)	Treat skin site-(b)	Blood	Carcass	CW/CW	Urine	Feces	Total recovery	Dermal absorption-(c)	Adjusted dermal abs-(d)
Group 6*	0.5	89.19	10.1	0	0.76	0	0	0	100	10.86	10.86
1.23 ug/cm2	1	91.46	8.77	0	0	0	0.03	0	100	8.80	8.80
(0.015 mg/animal)	2	92.85	7.14	0.01	0	0	0.03	0	100	7.18	7.18
	4	93.14	6.74	0.01	0	0.03	0.17	0	100	6.95	6.95
	10	88.7	10.7	0.01	0.11	0.1	0.35	0	100	11.27	11.27
	24	87.15	10.8	0.03	0.38	0.32	1.14	0.21	100	12.88	12.88
	120	84.51	9.29	0	0	0.92	3.95	1.35	100	15.51	15.51

CW/CW - cage wash/cage wipe

(a) sum of the percent dose recovered from the non-occlusive cover, enclosure rinse, skin wash.

(b) washed at each sacrifice time, except for the 24 and 120-hour sacrifice times where washing was done 10 hours post dosing.

(c) sum of percent dose recovered in the treated skin site, blood, carcass, CW/CW, urine, feces.

(d) "(c)" was adjusted to reflect a 100% recovery of the administered dose.

* calculation of percent dose was based on the actual administered dose for each animal.

Table A2. Percent dose of deltamethrin excreted following 10-hour exposure.

		Percent dose recovered in excreta (mean)			
Dose group 4	Time (hour)	Urine	Feces	Total	Cumul total
136 ug/cm2	24	0.41	0.08	0.49	0.49
	48	0.52	0.18	0.7	1.19
	72	0.4	0.16	0.56	1.75
	96	0.27	0.12	0.39	2.14
	120	0.16	0.11	0.27	2.41
	Total	1.76	0.65	2.41	

		Percent dose recovered in excreta (mean)			
Dose group 5	Time (hour)	Urine	Feces	Total	Cumul total
44 ug/cm2	24	0.51	0.16	0.67	0.67
	48	0.61	0.26	0.87	1.54
	72	0.31	0.23	0.54	2.08
	96	0.4	0.29	0.69	2.77
	120	0.25	0.11	0.36	3.13
	Total	2.08	1.05	3.13	

Table A2 (cont,). Percent dose of deltamethrin excreted following 10-hour exposure.

		Percent dose recovered in excreta (mean)			
Dose group 4	Time (hour)	Urine	Feces	Total	Cumul total
1.23 ug/cm2	24	1.43	0.29	1.72	1.72
	48	1.11	0.47	1.58	3.3
	72	0.64	0.26	0.9	4.2
	96	0.46	0.21	0.67	4.87
	120	0.31	0.12	0.43	5.3
	Total	3.95	1.35	5.3	

Table A3. Summary: dermal absorption of deltamethrin in male rats after ten-hour exposure.

Dose	Percent of dose recovered						
mg/animal (ug/cm2)	Excreted*	CW/CW	Carcass	Blood	Subtotal	Recover	Total absorp**
1.7 (136)	3.22	0.52	0.08	0	3.82	104	3.7
0.551 (44)	5.13	1.12	0.15	0	6.4	98.7	6.5
0.015 (1.23)	5.86	0.92	0	0	6.78	100	6.8

* Values were derived from the exponential saturation model.

** Adjusted to reflect a recovery of 100%.

(TXL/Dermal/Deltamet)

Appendix B
(Tables B.1 - B.3)

Summary Statistics for Calculated Dermal Exposures for Mixer/loaders and Applicators During Groundboom Application and Flaggers During Aerial Application.

Exposure Data were Generated from Pesticide Handlers Exposure Database (PHED1995)

Table B.1 SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES - MIXER/LOADERS

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI Median	Mean	Coef of Var	Geo. Mean	Ob
MIXED						
HEAD (ALL)	Other	4.03	11.18	125.0322	6.8037	
NECK.FRONT	Lognormal	3.57	75.674	194.9734	6.106	
NECK.BACK	other	.341	54.5219	199.3111	3.2659	
UPPER ARMS	Lognormal	4.656	11.1712	136.9996	5.3387	
CHEST	Lognormal	5.68	14.91	126.6506	7.1269	
BACK	Lognormal	5.68	13.6281	137	6.5128	
FOREARMS	Lognormal	1.936	4.6451	136.9981	2.2199	
THIGHS	Lognormal	6.112	4.7113	53.8195	3.2376	
LOWER LEGS	Lognormal	3.808	2.9353	53.8207	2.Cl72	
FEET						
HANDS	Lognormal	.625	5.5854	307.3656	.53	
TOTAL DERM:		37.4601	36.438	198.9623	43.1587	
INHALATION:	Lognormal	4.375	11.8278	243.7748	2.1785	
COMBINED:		39.6386	40.813	210.7901	45.3372	

95% C.I. on Mean: Dermal: [-2784.2024, 3182.127)
95% C.I. on Geo. Mean: Inhalation: C.0695, 68.2876]
Inhalation Rate : 14 Liters/Minute
Number of Records: 30
Data File: MIXER/LOADER Subset Name: TEMP.NAME.MLOD

Table B.2 SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES - APPLICATORS

SCENARIO: Long pants, short sleeves, gloves

PATCH SPRAYED LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI median	Mean	Coef of Var	Geo. Mean	C
HEAD (ALL)	Lognormal	.78	5.7598	300.5764	1.1	
NECK.FRONT	Lognormal	.18	.52	163.8269	.1481	
NECK.BACK	other	.11	.654	319.0979	.1014	
UPPER ARMS	other	.291	.8289	127.5305	.5351	
CHEST	other	.71	5.1636	228.8035	1.3479	
BACK	other	.71	6.0439	225.7284	1.2721	
FOREARMS	Lognormal	1.331	4.112	163.339	1.2304	
THIGHS	Lognormal	.955	1.337	103.5303	.9238	
LOWER LEGS	Lognormal	.714	1.428	177.465	.7074	
FEET	Lognormal	4.323	4.1629	45.8935	3.66	
HANDS	Lognormal	.4546	12.6807	149.8734	1.7526	
TOTAL DERM:		11.3433	10.5586	42.6908	12.7788	
INHALATION:	Lognormal	.5119	4.6054	421.2425	.4206	
COMBINED:		11.7639	11.0705	47.2962	13.1994	

95% C.I. on Mean: Dermal: [-452.423, 537.8046]
95% C.I. on Geo. Mean: Inhalation: [.0036, 48.9811]
Inhalation Rate : 14 Liters/Minute
Number of Records: 86
Data File: APPLICATOR Subset Name: TEMP.NAME.APPL

Table B.3 SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES - FLAGGERS

SCENARIO: Long pants, short sleeves, gloves

PATCH SPRAYED LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI Median	Mean	Coef of Var	Geo. Mean	Ob
HEAD (ALL)	Lognormal	.65	.7511	75.3295	.6372	9
NECK.FRONT	Lognormal	.06	.065	25.8462	.0626	9
NECK.BACK	Lognormal	.055	.0758	110.686	.0568	9
UPPER ARMS	Lognormal	1.3095	1.3459	16.0859	1.3314	8
CHEST	Lognormal	1.42	1.5383	25.8012	1.4816	9
BACK	Lognormal	1.42	1.5383	25.8012	1.4816	9
FOREARMS	Lognormal	.484	.9008	139.7758	.5688	9
THIGHS	Lognormal	1.719	1.7668	16.0856	1.7478	8
LOWER LEGS	Lognormal	1.071	1.1008	16.0883	1.0889	8
FEET						
HANDS	Lognormal	1.5714	1.5723	18.9022	1.551	4
TOTAL DERM:		10.0077	9.7599	10.6551	10.0077	
INHALATION:	Other	.0388	.1156	145.8478	.0585	9
COMBINED:		10.0465	9.7987	10.7707	10.0662	

95% C,.I. on Mean: Dermal: [-19.6711, 40.9813]
95% C.I. on Geo. Mean: Inhalation: [.0069, .4925]
Inhalation Rate : 14 Liters/Minute
Number of Records: 9

Data File: FLAGGER Subset Name: TEMP.NAME.FLAG